

**REMARKS**

Claims 1-2, 4-5, 9-12, 16, 21-43, 48, 50-54, 56-57 and 62-69 are pending. Claims 3, 8, 17-20 and 46-47, 49 and 55 have been canceled without prejudice. Applicants expressly reserve the right to pursue the canceled subject matter in this application or subsequent applications that claim the benefit of this application. Claims 1, 5, 24, 48, 54 and 57 have been amended to recite that mesenchymal stem cells are enriched from bone marrow mononuclear cells at least two-fold prior to administration to the subject. Support for the amendment may be found, *inter alia*, in the specification on page 13, line 26 to page 14, line 3. Claim 12 has been amended to delete "CD133+/CD34+". These amendments do not enter any new matter.

Applicants request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

**DETAILED ACTION**

**Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

Claims 12 and 46 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleges that claim 12 includes embodiments that are CD34+ but not CD133+ and claim 46 does not further limit claim 1.

Applicants have amended claim 12 to remove the second recitation of CD133+,CD34+. Applicants have canceled claim 46. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

**Rejections under 35 U.S.C. § 103(a)**

Claims 1-4, 8, 10-12, 17, 19-21, 23-36, 40-43, 46-47, 49-57, and 62-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strauer et al. (2002, *Circulation* 106: 1913-1918) taken in view of Ueno et al. (US Patent Application Publication 2002/0037278), Kocher et al. (2001, *Nature*

*Medicine* 7: 430-436), and Itescu (US Patent Application Publication 2003/0199464). Applicants traverse in light of the amended claims.

Applicants disagree with the rejection, but nonetheless, solely to expedite prosecution, applicants have amended claims 1, 5, 24, 48, 54 and 57 to recite that mesenchymal stem cells are enriched from bone marrow mononuclear cells at least two-fold prior to administration to the subject. Support for the amendment is found on page 13, line 26 to page 14, line 3. Strauer et al. discloses that MSCs and EPCs are populations among multiple fractions of bone marrow mononuclear cell types that may contribute to regeneration. Strauer et al. decided to use the entire heterogeneous mononuclear cell population because it was not clear which fraction had regenerative potential (see first paragraph, page 1917). It would not have been obvious to one of ordinary skill in the art to enrich the CD133+/CD34+ cells and the MSCs from bone marrow mononuclear cells at least two-fold based on Strauer et al.

Strauer et al. alone or in combination with the cited secondary references do not teach or suggest each of the limitations of the present claims as amended and thus fail to render obvious the claimed subject matter. Reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) are respectfully requested.

### **Double Patenting**

Claims 1-4, 8, 10-12, 17, 19-21, 23-28, 35, 40-43, 46-47, 49-57, and 62-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being obvious over claims 1, 3, 8, 9, 11-16 and 18-26 of copending Application No. 10/875,643.

Applicants request that this rejection be held in abeyance until notification of allowable subject matter.

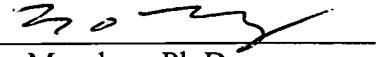
**CONCLUSIONS**

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants believe no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. CWRU-P01-046 from which the undersigned is authorized to draw.

Dated: July 14, 2008

Respectfully submitted,

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